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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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MORGAN, LEWIS & BOCKIUS, LLP ONE MARKET SPEAR STREET TOWER SAN FRANCISCO, CA 94105			EXAMINER TURK, NEIL N	
			ART UNIT 1797	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/653,032

Applicant(s)

DASGUPTA ET AL.

Examiner

Neil Turk

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 September 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10, 12-26 and 28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10, 12-26 and 28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 4/14/04 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Remarks

This Office Action fully acknowledges Applicant's remarks filed on September 24th, 2007. Claims 1-10, 12-26, and 28 are pending. Claims 11 and 27 have been cancelled. Any objection/rejection not repeated herein has been withdrawn by the Office.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the structural features of the claims must be shown or the feature(s) canceled from the claim(s). No new matter should be entered. The new replacement drawing sheets, which delete figures 1-1c, lack clarity from their lack of relevant structural description in the specification (i.e. Examples 1 and 7) that would correlate to the elements of the claims claims. **New figure 8a** is the only figure which appears to be drawn to the apparatus, and the figure is unlabeled with respect to the claimed structural elements throughout the claims. The drawings appear to show some sort of flow cell with inlets and outlets, but absent labeling and a proper description in the specification it is unclear how the drawings relate to the claimed elements. Further, **new drawings 9-10c** are illegible.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate

prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 12-26, and 28 recite the limitation "said treating method". There is insufficient antecedent basis for this limitation in the claim.

Claims 16 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 16 recites, in relevant part, "...said method

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further comprises separating said one and second analyte ion species in said sample stream prior to said treating method". Beyond the fact that "said treating method" lacks proper antecedent basis, the claim is indefinitely defined. The claim does not properly establish further limitations to the method as it is not possible for a further step to the previously recited method to be a prior step taken before the method.

Claims 23 and 24 respectively recite that the liquid interface is disposed substantially horizontally and substantially vertically. Without further structural limitations to the apparatus which would require such an orientation, the device may be viewed in a different orientation so as to meet the limitations of the interface being horizontally or vertically disposed. This is further because the horizontal and vertical disposition being claimed is not relative to any certain aspect so as to give a particular structural orientation.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 4-9, 12-21, and 23-26, and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Yager (5,971,158).

Yager discloses an absorption-enhanced differential extraction device for use in affinity chromatography. Yager discloses a device and method for extracting desired particle from a sample stream containing the desired particles. Yager discloses that the device has a sample stream inlet, an extraction stream inlet, and an extraction channel (treatment channel) in fluid communication with the sample stream inlet and extraction stream inlet. Yager discloses that the extraction channel is for receiving a sample stream (such as those listed in lines 1-17, col. 8) in adjacent laminar flow with an extraction stream (comprised of an organic solvent, see lines 17-29, col. 7), wherein the extraction channel is provided with a sequestering material (matrix ion species capture material) to capture desired particles (particles defined to include ions, see lines 19-26, col. 6). Yager further discloses that a bi-product stream outlet in fluid communication with the extraction channel receives a by-product stream comprising at least a portion of the sample stream from which desired particles have been extracted (concentration lower at the outlet than at the inlet). A product outlet in fluid communication with the extraction channel receives a product, which has the sequestering material and at least a portion of the desired particles (abstract). Yager discloses that the sequestering material can be present in the extraction stream prior to the extraction stream's being introduced into the extraction channel, or the sequestering material can be added to the extraction stream by suspending or dissolving the sequestering material in a liquid which is introduced into the extraction stream (lines 40-46, col. 4). Yager also discloses that the sequestering material provides for increased diffusion of the desired particles (lines 47-52, col. 5). Yager also discloses that the sample and extraction streams are

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kept in contact in the extraction channel for a period of time sufficient to allow at least an analyzable quantity, and even small amounts of analytes present may be detected by spectroscopic and other means (line 53, col. 9 – line 5, col. 10). Yager further discloses that the invention may be utilized as a sample pretreatment system for an analytical system including sensing means for detecting desired particles in the product and by-product streams (Examiner asserts that at least a portion of the sample steam inherently flows through). Yager discloses detection means include optical means such as spectroscopic equipment, and means for detecting fluorescence, chemical indicators, and also any magnetic resonance equipment or other means known to detect the presence of analyte particles such as ions (lines 36-57, col. 11). Yager further discloses various embodiments of extraction devices in columns 13-15.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-10, 12-26, and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rocklin (4,751,189) in view of Yager.

Rocklin discloses a method of ion chromatography. Rocklin discloses that the system is useful for determining a large number of ionic species, such as anions and cations. Rocklin discloses that a suitable sample includes surface waters, chemical wastes, body fluids, and beverages such as fruits and wines and drinking water. Rocklin discloses that the term ionic species includes species in ionic form and components of molecules, which are ionizable under the conditions of the system (lines 53-62, col. 2). Rocklin shows in figure 1 an eluent reservoir 14 and sample 13 injected to a chromatographic separation means, such as a chromatographic column 10 which is packed with a separation medium, such as an ion-exchange resin. Rocklin discloses that arranged in series with the column 10 is a suppressor means 11 serving to suppress the conductivity of the eluent from column 10 but not the conductivity of the

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separated ions (lines 13-34, col. 3, fig. 1). The effluent from suppressor means 11 is directed to a detector in the form of a conductivity cell 12 for detecting all of the resolved ionic species (lines 35-54, col. 3). Rocklin discloses that in one embodiment of the suppressor device 17, effluent from the chromatographic column is directed through the effluent flow channel 26 (treatment channel) bounded on both sides by ion-exchange membranes 27, and the ion-exchange membranes are preferably permeable to ions of the same charge as the exchangeable ions of the membrane and resists permeation of ions of opposite charge. Rocklin further discloses that the membranes are simultaneously contacted on their outsides with the regenerate flowing in the opposite direction through the regenerate flow channels 28. Ions extracted from the effluent (sample stream) at the active ion-exchange sites of the membranes are diffused through the membranes and are exchanged with ions of the regenerate (carrier stream), and thus diffused ultimately into the regenerate (lines 8- 44, col. 4). Rocklin discloses that a suitable regenerate solution is dilute sulphuric acid (lines 28-37, col. 5).

Rocklin does not disclose a matrix ion species capture material included in the carrier stream.

Yager has been discussed above.

It would have been obvious to modify Rocklin to include a sequestering material in the carrier stream such as taught by Yager in order to provide a means for increasing diffusion of the desired particles while no longer requiring the added elements of the ion exchange membranes in the flow channels.

Claims 9 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yager in view of Kais.

Yager has been discussed above.

Yager discloses the use of various solvents for the carrier liquid. Yager also discloses various sample streams for use within the device that are immiscible with the various organic solvents disclosed. Yager does not specifically disclose any specific pairs of solvent and sample stream which are immiscible with each other.

Kais discloses a column chromatography technique. Kais discloses that the dynamic chromatography can be utilized also in liquid ion exchangers, such as in liquid-liquid extraction systems. Kais discloses that liquid-liquid extraction operates in a manner by interchange of ions at the interface between an aqueous solution and an immiscible solvent with negligible distribution of the extractant to the aqueous phase (lines 3-10, col. 8).

It would have been obvious for Yager to choose a given solvent and a sample stream that is immiscible with the given solvent such as taught by Kais in order to provide a liquid-liquid extraction system for interchange of ions in which there is negligible distribution of the extractant to the aqueous phase.

Response to Arguments

Applicant's arguments filed September 24th, 2007 have been fully considered but they are not persuasive.

With regards to claims 23 and 24 rejected under 35 USC 112, 2nd paragraph, Applicant argues that the horizontal and vertical disposition of the liquid interface, respectively recited in claims 23 and 24, is all that is necessary to define the method. Examiner asserts that claims 23 and 24 are indefinitely defined for such respective dispositions, as it is unclear what further structure/steps is/are incorporated to arrive at the respective dispositions.

With regards to **claims 1, 2, 4-9, 11-21, and 23-28** rejected under 35 U.S.C. 102(b) as being anticipated by Yager (5,971,158), Applicant argues that Yager does not meet the claim limitations. **With regard to claim 1**, Applicant argues that Yager does not teach detecting the analyte ion species in the sample stream. Examiner asserts that claim 1 does not require the analyte ion species to be detected in general, and further does not require the analyte ion species to be detected in the sample stream.

With regard to claim 2, Applicant argues that claim 2 recites a detector for the at least one analyte ion species in the sample stream and a fluid conduit providing fluid communication between the sample treatment outlet and the detector with the sample stream flowing through the conduit. Examiner asserts that the recitation with respect to the detector, which reads, "a detector for said at least one analyte ion species in said

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sample stream" is drawn to a functionality of the detector to detect at least one analyte ion species in the sample stream and does not structurally place the site of the detection (by the detector) in the sample stream. Examiner asserts that the analyte ions detected in Yager come from the sample stream, and as such the detector(s) recited in Yager have the same functionality of detecting at least one analyte ion species in the sample stream such that the analyte ions come from the sample stream. Examiner further asserts that at least a portion of the sample stream will inherently flow through the conduit.

With regard to claim 14, Applicant argues that Yager does not disclose that the analyte ion species is detected in the sample stream. Examiner asserts that Yager discloses that the invention may be utilized as a sample pretreatment system for an analytical system including sensing means for detecting desired particles in the product and by-product streams, in which the by-product stream includes the sample stream (abstract; col. 11). Examiner asserts that the detection in the by-product stream, which includes the sample stream, constitutes detecting the one analyte ion species in the sample stream.

With regard to claim 15, Applicant argues that Yager does not disclose that the sample and carrier liquid stream exiting the treatment channel are separated prior to detection. Examiner argues that Yager discloses that the streams may be separated at the end of the conduit at any arbitrary location by precise regulation of the exit flow rate of the outlets (lines 13-15, col. 7).

With regards to claims 1-28 rejected under 35 USC 103(a) as being unpatentable over Rocklin (4,751,189) in view of Yager, Applicant argues that such a combination is not proper.

Applicant argues that Yager is directed toward a solution of an entirely different problem using an entirely different approach in comparison to the invention of the present claims. Applicant argues that Yager removes analyte ions from the sample liquid stream to the carrier liquid stream for detection to free it from contaminants in the sample liquid stream. Applicant asserts that in contrast, Rocklin removes matrix ions across an ion exchange member while detecting the liquid stream, and asserts that there is no suggestion of modifying Rocklin to use the liquid-liquid interface of Yager, which teaches a different method performed for a different purpose. Examiner argues that the combination of Rocklin in view of Yager is not modified with respect to the detection of the ions in any particular stream. Examiner asserts that both Rocklin and Yager disclose separation systems which remove matrix ions. Thereby, the sequestering material of Yager would be an obvious modification to Rocklin so as to replace the elements of the ion exchange membranes in the flow channels of Rocklin, while also increasing diffusion of the desired particles.

With regards to claims 9 and 21 rejected under 35 USC 103(a) as being unpatentable over Yager in view of Cais et al. (4,510,058), Applicant argues that such a combination is not proper.

Applicant remarks that the advantages of using immiscible sample and carrier liquid streams are set forth at pages 10-12 of the specification. Applicant contends that there is no suggestion in Cais of such advantages of using immiscible liquids. Examiner asserts that it is not required that Cais disclose that of which is disclosed in Applicant's specification at pages 10-12.

Examiner asserts that Yager discloses the use of various solvents for the carrier liquid. Yager also discloses various sample streams for use within the device that are immiscible with the various organic solvents disclosed. Kais discloses that the chromatography technique disclosed can also be utilized in liquid ion exchangers, such as liquid-liquid extraction systems. Kais further discloses that the liquid-liquid extraction operates in a manner by interchange of ions at the interface between an aqueous solution and an immiscible solvent with negligible distribution of the extractant to the aqueous phase. Thereby, as Yager discloses a liquid-liquid extraction system and discloses various organic solvents and sample streams for use with the device that are immiscible in such solvents, it would have been obvious to modify the liquid-liquid extraction system of Yager by that of the liquid-liquid extraction of Kais which utilizes a solvent and sample stream that are immiscible with each other, so as to provide for interchange of ions with negligible distribution of the extractant to the aqueous phase.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Neil Turk whose telephone number is 571-272-8914.


The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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NT


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